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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,032	09/20/2001	Alan J. Lang	D-2821CON	6533
7590	12/29/2003		EXAMINER	
Frank J. Uxa Stout, Uxa, Buyan & Mullins, LLP Suite 300 4 Venture Irvine, CA 92618			CHATTOPADHYAY, URMJ	
			ART UNIT	PAPER NUMBER
			3738	
			DATE MAILED: 12/29/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,032

Applicant(s)

LANG, ALAN J.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/14/03 as been entered as Paper No. 11. Claims 46-64 have been cancelled (claims 1-45 were already cancelled from previous amendments). New claims 65-69 have been added.

Terminal Disclaimer

2. The terminal disclaimer filed on 6/17/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 09/302,977 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

3. Claim 68 is objected to because of the following informalities: in line 1, "mutlifocal" should be changed to --multifocal--. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 67-69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 67 structurally defines the IOL as including a human lens,

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which is non-statutory subject matter, to provide an optical system. The examiner suggests changing “operationally functioning” in line 2 to --adapted to operationally function--.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 65-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following claim limitations are considered new matter:

a. Claim 65, line 3, “the optical surface is coupled to at least two haptic fixation members” because (a) page 5, line 24 and page 15, lines 14-15 disclose the fixation members being coupled to the lens body, not specifically the optical surface, and (b) page 5, lines 23-24 discloses “a fixation member or members” and the figures show exactly two fixation members; there is no disclosure of *at least* two haptic fixation members.

b. Claim 66, line 4, “hybrid materials composed of a combination of silicone and acrylic” because page 9, lines 4-13 do not disclose this hybrid as a material for the lens or the fixation members.

c. Claim 67, lines 1-2, “at least one optical power further comprises only one near power”.

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d. Claim 68, lines 1-2, "said lens maximizes the areas of the involved optical system for usable vision".

e. Claim 69, lines 1-2, "said optical system is effective for presbyopic refractive error correction".

Applicant must either amend the claims by canceling the new matter or provide references to specific pages and line numbers that clearly show these limitations were indeed disclosed in the original specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 65 is indefinite because on line 1, the word "phakic" is being used to describe an intraocular lens. An IOL cannot be phakic. It appears that the applicant is trying to claim that the multifocal IOL is used in a phakic eye, which is defined in applicant's specification on page 1, lines 5-6 as an eye which includes the natural lens.

9. Claim 67 is indefinite. Is the "at least one optical power" on lines 1-2 referring to the at least one optical *add* power? It is unclear if the at least one optical (add) power comprises only one near add power or only one near diopter power. It is unclear what is functioning in conjunction with the human lens as an optical system. Is it the only one near (add or diopter) power or the at least one optical (add) power? It is unclear if "with a power" is referring to the

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only one near (add or diopter) power or the at least one optical (add) power or the optical system? Claim 67 is also unclear because how can a power be intermediate to the at least one optical add power? For something to be intermediate, it must be in between two things. In claim 67, a second reference power is missing from the limitation. Applicant is reminded that the optical system is defined only when the IOL is operationally functioning with the human lens. The optical system is not a structural limitation of the IOL. Also, the IOL cannot structurally claim the natural lens as part of the IOL. Clarification is required without introducing any new matter.

10. Claim 68 is indefinite because it is unclear what is considered "areas involved in the optical system".

11. Claims 68 and 69 are indefinite because it is unclear how the claimed invention of multifocal IOL is being further limited. Again, the optical system is not a structural part of the IOL, and the IOL cannot claim the natural lens as a structural part of it. The examiner suggests rewriting the claim using functional language with respect to the IOL.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. Claims 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menezes et al. (USPN 5,847,802 as cited in applicant's IDS) in view of Portney (USPN 6,197,058 as cited in applicant's IDS).

Menezes et al. discloses an intraocular lens with all the elements of claim 65, but is silent to at least two fixation members coupled to what the examiner is interpreting as the lens body. See column 1, lines 22-25 and Figure 1 for a multifocal intraocular lens for use in an eye having a natural lens (column 4, lines 52-53, wherein the statement that "*Some patients may not require the full...add power in these designs.*" clearly suggests use with the natural lens of the eye, otherwise full add power correction would be necessary for full near vision). The lens has an optical surface having a baseline optical power (12) and at least one optical add power (14) (column 3, lines 62-65 and column 4, lines 19-24). Portney teaches an IOL with two fixation members coupled to the lens body in order to attach the IOL to the eye, as shown in Figure 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Portney to modify the IOL of Menezes et al. to include two fixation members coupled to the lens body in order to attach the IOL to the eye. Menezes et al. is also silent to the IOL comprising silicone, acrylic or a combination thereof, as required by claim 66. Portney teaches making the lens from a silicone or acrylic material in order for the lens to be elastically deformable for insertion into an individual's eye through a small ocular incision. See column 4, lines 36-39. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Portney to modify the IOL of Menezes et al. by having the IOL comprise silicone or acrylic in order to make the lens elastically deformable for insertion into an individual's eye through a small ocular incision.

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Claim 67, see Figure 1 for what the examiner is interpreting as the at least one optical *add* power comprising only one near *add* power (N). See column 4, lines 52-53, wherein the statement that “*Some patients may not require the full...add power in these designs.*” clearly suggests use with the natural lens of the eye, otherwise full add power correction would be necessary for full near vision. Menezes et al. further discloses that when full add power is not required, the near power can be made a fraction (preferably 50%) of the full add power (column 4, lines 52-55). Since the at least one optical add power of the IOL is made to be a fraction of the full add power, the at least one optical add power is clearly functioning in conjunction with the natural lens as an optical system to provide full near vision correction.

With respect to claims 68 and 69, see rejections to claims 65 and 67, *supra*. Because the IOL meets the claimed structural limitations, as best interpreted by the examiner, the lens is *capable* meeting the functional limitations of maximizing the areas of the involved optical system for useable vision and correcting presbyopic refractive error when the IOL is used in the phakic eye.

14. Claims 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn (WO 97/12272 A1, as cited in applicant’s IDS) in view of Portney (USPN 6,197,058 as cited in applicant’s IDS).

Dunn discloses an intraocular lens with all the elements of claim 65, but is silent to at least two fixation members coupled to what the examiner is interpreting as the lens body. See page 22, lines 2-3 for a multifocal intraocular lens for use in an eye having a natural lens (page 7, lines 31-35, wherein the statement that “*It is therefore an object of this invention to provide true*

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multifocal correction for moderate and mature presbyopes...” clearly suggests use with the natural lens of the eye with natural lens having natural accommodative capability). The lens has an optical surface having a baseline optical power (zone 4; page 8, lines 21-23 and page 14, lines 23-28, wherein zone 4 being “*corrected for distance vision*” meets applicant’s definition of the baseline power being “the power required for far vision for an IOL” on page 12, lines 16-17 of the specification) and at least one optical add power (Figure 1, zone 2; page 9, lines 3-15).

Portney teaches an IOL with two fixation members coupled to the lens body in order to attach the IOL to the eye, as shown in Figure 3. It would have been obvious to one of ordinary skill in the art at the time of applicant’s invention to look to the teachings of Portney to modify the IOL of Dunn to include two fixation members coupled to the lens body in order to attach the IOL to the eye. Dunn is also silent to the IOL comprising silicone, acrylic or a combination thereof, as required by claim 66. Portney teaches making the lens from a silicone or acrylic material in order for the lens to be elastically deformable for insertion into an individual’s eye through a small ocular incision. See column 4, lines 36-39. It would have been obvious to one of ordinary skill in the art at the time of applicant’s invention to look to the teachings of Portney to modify the IOL of Dunn by having the IOL comprise silicone or acrylic in order to make the lens elastically deformable for insertion into an individual’s eye through a small ocular incision.

Claim 67, see Figure 1 for what the examiner is interpreting as the at least one optical *add* power comprising only one near *add* power (zone 2). See page 7, lines 31-35, wherein the statement that “*It is therefore an object of this invention to provide true multifocal correction for moderate and mature presbyopes...*” clearly suggests use with the natural lens of the eye with natural lens having natural accommodative capability. The near optical add power (zone 2) has a

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magnitude so as to provide, in combination with the natural accommodative capability of the natural lens, enhanced vision (page 14, lines 29-36, wherein the assignment of a low add power for early to moderate presbyopia and a high add power to moderate to advanced presbyopia clearly suggests that the accommodative capability of the natural lens is being taken into account in choosing the appropriate add power to provide enhanced vision). Therefore, the at least one optical add power is clearly functioning in conjunction with the natural lens as an optical system to provide full near vision correction.

With respect to claims 68 and 69, see rejections to claims 65 and 67, *supra*. Because the IOL meets the claimed structural limitations, as best interpreted by the examiner, the lens is *capable* meeting the functional limitations of maximizing the areas of the involved optical system for useable vision and correcting presbyopic refractive error when the IOL is used in the phakic eye.

Response to Arguments

15. Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies [i.e., distance vision for moderately bright light where the human pupil is between about 2.5mm and 4mm, and distance *and* low-add (near) vision] are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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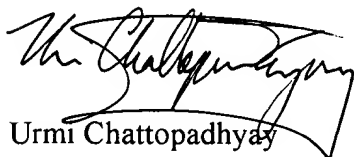
Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David H. Willse
Primary Examiner